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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,667	08/27/2001	Jens Petersen	60117.000006	2505

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/25/2004

Stanislaus Aksman
Hunton & Williams
Suite 1200
1900 K Street, N.W.
Washington, DC 20006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,667	PETERSEN	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7, 9-20, 23, 24, 26, 28-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-15,17-20,23,24,26 and 28-49* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/09/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt for request for continued examination under 37 C.F.R. 1.114 filed 12/08/03. The amendment submitted 10/09/03 has been entered upon the filing of the request for continued examination under 37 C.F.R. Claims 1-7, 9-20, 23, 24, 26 and 28-49 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/08/03 has been entered.

Information Disclosure Statement

2. Page 2 of the information disclosure statement filed 10/09/03 is not considered because application serial number 10/227,265 is identified as the application for which the page 2 of the PTO Form 1449 refers to. It is respectfully suggested that applicant submit a PTO Form 1449 that identifies the proper application number if the references cited on the page 2 are to be considered for the examined application number 09/938,667.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 18, 20, 26, 28, 41-46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Pavlyk (RU 2034465, provided by applicants).

Pavlyk discloses hydrogel composition where the polymer contains 3.5-9% acrylamide, methylene-bis-acrylamide 0.001-1% and about 82% bi-distilled water (English abstract). The viscosity recited in instant claims is an inherent property of the composition. Instant claim 6 is directed to a future intended use of the composition, and in a composition claim the future intended use has no patentable weight. Thus the claims directed to the future intended use of the composition read on the composition. Pavlyk does not refer to the presence of monomeric units in the composition and there is not disclosed that monomeric units is greater than 50 ppm. The ratio of acrylamide to methylene bis-acrylamide falls within the ratio of 150:1 to 1000:1 recited in instant claim 2. Pavlyk meets the limitations of the claims.

5. Claims 1, 3, 5, 6, 18, 20, 26, 41, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/04943 (provided by applicants).

The WO 96/04943 discloses hydrogel composition that comprises between 3.5 and 9% polymer where the polymer is cross-linked polyacrylamide, and where the cross-linking agent is methylene bis-acrylamide (English abstract). The viscosity recited in instant claims is an inherent property of the composition. Instant claim 6 is directed to a future intended use of the composition, and in a composition claim the future intended use has no patentable weight. Thus the claims directed to the future intended use of the composition read on the composition. WO 96/04843 does not refer to the presence of monomeric units in the composition and there is not disclosed that monomeric units is greater than 50 ppm. WO 96/04943 meets the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-7, 9-15, 18-20, 23, 24, 26, 28-36, 41-49 rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028).

Vogel teaches a method for treating urinary incontinence by administering a pyrogen free composition and the composition comprises hydrophilic polyacrylamide or its derivatives and methylene-bis-acrylamide (abstract and column 7, lines 6-22). Although, Vogel does not refer to the composition as hydrogel, a composition formed from acrylamide monomer and methylene bis-acrylamide cross-linking agent is a hydrogel, because it is known that polyacrylamide monomers cross-linked with methylene bis acrylamide is a hydrogel (see Halpern et al., US 3,867,329, column 2, line 33 to column 3 line 18). Vogel is silent on the viscosity of the hydrogel composition. But one of ordinary skill in the art would know routine method of measuring/determining the viscosity of a hydrogel composition. The viscosity of the hydrogel composition is a property of the composition and the property of a composition cannot be separated from the composition. There is no showing that the viscosity of the composition provides unusual results over the composition of the prior art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Vogel. One having ordinary skill in the art would have been motivated to prepare the composition of Vogel and administer it to treat urinary incontinence in a subject in need thereof the expectation that the composition would be effectively administered to treat urinary incontinence.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-7, 9-15, 18-20, 23, 24, 26 and 28-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of copending Application No. 09/938,668 (published as US 2003/0065389). Although the conflicting claims are not identical, they are not patentably distinct from each other because the having monomeric units of less than 50 ppm does not distinguish the examine application over the co-pending application. The composition of the polymer is the same in both applications and administering the composition would inherently treat arthritis and incontinence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-7, 9-15, 18-20, 23, 24, 26 and 28-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 09/938,669 (published as US 2002/0150550). Although the conflicting claims are not identical, they are not patentably distinct from each other

because the polymeric compositions of both applications are the same and having monomeric units of less than 50 ppm does not distinguish the examined application over the co-pending application. The composition of the polymer is the same in both applications and the compositions can be used as tissue filler endoprosthesis as well as for treating incontinence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-7, 9-15, 17-20, 23, 24, 26 and 28-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 09/938,670 (published as US 2002/0064512). Although the conflicting claims are not identical, they are not patentably distinct from each other because the polymeric compositions of both applications are the same and having monomeric units of less than 50 ppm does not distinguish the examined application over the co-pending application. The composition of the polymer is the same in both applications and the compositions can be used for treating cosmetic or functional defect as well as for treating incontinence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 16 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose injecting the composition at the recited positions.

13. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600